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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/263,689	03/05/1999	JIAN NI	1488.0560002	2137

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EXAMINER	
CANELLA, KAREN A	
ART UNIT	PAPER NUMBER
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/263,689	NI ET AL.	
	Examiner	Art Unit	
	Karen A. Canella	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *141-144 and 146-172* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *141-144, 146-172* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 166 has been amended. Claim 145 has been canceled. Claims 141-144 and 146-172 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 141-144 and 146-172 under 35 U.S.C. 101 is maintained for reasons of record, because the claimed invention is not supported by either a specific, substantial asserted utility or a well-established utility. The instant invention is drawn to the protein of SEQ ID NO:4 and fragments of SEQ ID NO:4 which consist of at least 30 or 50 contiguous amino acid sequence of SEQ ID NO:4 as well as specific antigenic fragments of SEQ ID NO:4, predicted by the specification to have antigenic activity such as residues 62-102 of SEQ ID NO:4, residues 226-259 of SEQ ID NO:4 and residues 197-308 of SEQ ID NO:4. The specification identifies SEQ ID NO:4 as belonging to the Galectin family of proteins recognized to have the ability to bind beta-galactoside in a calcium-independent manner. The art teaches that members of this class are distinguished from other lectins by the presence of a conserved carbohydrate recognition domain. The instant specification lacks a specific , substantial asserted utility because it fails to provide for a non-ambiguous usage of the claimed protein. On page 27, lines 20-25, the specification states

It is believed that certain tissues in mammals with certain diseases (cancer, autoimmune diseases, inflammatory diseases, asthma, and allergic diseases) express significantly altered (enhanced or decreased) levels of the galectin 8, 9, 10, or 10SV protein and mRNA encoding the galectin 8, 9, 10, or 10SV protein when compared to a corresponding "standard" mammal, i.e., a mammal of the same species not having the disease.

It is noted with particular emphasis that the specification fails to assert if the claimed protein is over-expressed or under-expressed in any of the stated diseases. Because of this defect

the stated utility is neither specific nor substantial because the condition of perhaps being over expressed or perhaps being under-expressed does not provide for a specific, substantial assertion.

It is further noted that the specification contemplates on page 29, lines 3-5,

The present invention is useful for detecting diseases in mammals (for example, cancer, autoimmune diseases, inflammatory diseases, asthma, and allergic diseases), and on page 30, lines 14-18,

The ability of galectin 8, 9, 10, or 10SV to modulate growth regulatory activity may be therapeutically valuable in the treatment of clinical manifestations of such cell regulatory disorders. Disorders which can be treated include, but should not be limited to, autoimmune disease, cancer (preferably, melanoma, renal, astrocytoma, and Hodgkin disease), inflammatory disease, wound healing, arteriosclerosis, other heart diseases, microbe infection (virus, fungal, bacterial, and parasite), asthma, and allergic diseases.

However, no further information is given with regard to detecting an over expression or an under expression of SEQ ID NO:4 for the detection of cancer, autoimmune diseases, inflammatory diseases, asthma, and allergic diseases in mammal and no further information is given with regard to the need to decrease or increase the level of SEQ ID NO:4 for the treatment of autoimmune disease, cancer, inflammatory disease, wound healing, arteriosclerosis, other heart diseases, microbe infection , asthma, and allergic diseases. Further, as stated in the Office action of February 1, 2001 (page 4, line 15 to page 5, line 2), membership in the family of galectins does not confer a specific substantial utility to the instant SEQ ID NO:4 because the family encompasses proteins having widely different functions. Further, the ability to bind beta-galactoside in a calcium-independent manner does not provide a specific, substantial utility because that property is shared by numerous proteins of the galectin family, which as stated above, have widely differing functional attributes. It is therefore concluded that the instant specification lacks a specific, substantial and asserted utility for SEQ ID NO:4.

The rejection of Claims 141-144 and 146-172 under 35 U.S.C. 112, first paragraph is maintained for reasons of record, because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, and one skilled in the art clearly would not know how to use the claimed invention is therefore maintained for reasons of record.

Applicant argues that the examiner is requiring the specific disclosure of a mechanisms of action in order to satisfy the utility requirement. Applicant is misconstruing the examiners analysis of the invention. Clearly, utility can be established by either empirical or non-empirical means. In the instant case, the specification lacks any empirical, actual demonstration of a substantial utility. Thus, the question of utility must be resolved by theoretical means. The specification links the claimed sequences with asthma. However, this is not a specific utility because being linked in some way to a disease such as asthma does not establish a specific utility because the positive or negative impact of the sequence on the disease has not been asserted. Because the specification is lacking any other assertion or demonstration of utility and the specification does not assert a specific substantial utility, stating that the polypeptides of the invention are either over expressed or under expressed in conditions of asthma, such that the specific, substantial nature of the polypeptides are not asserted. Applicant again refers to the post filing references which corroborate treatment and diagnosis of asthma. However, the post-filing references cannot overcome the deficiency of the specification in its lack of an assertion of specific and substantial utility.

Applicant argues that only one utility need be asserted in order to fulfill the statue under 35 U.S.C. 101. This is correct. However, the specification does not set forth an other specific, and substantial utility for the inventive polypeptides. Applicant argues that the specification clearly asserts several other utilities for the claimed polypeptides, but fails to state where this assertion is set forth in the specification.

The rejection of claims 141-144 and 146-172 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is maintained for reasons of record. The claim(s) contains subject matter which was not described in the specification in such a way as to

enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention..

The specification states on page 26, lines 16-19 that antigenic-epitope bearing peptides and polypeptides of the invention preferably contain a sequence of at least seven, more preferably at least nine, and most preferably between about 15 to about 30 amino acids. Claims 166 and 168-172 encompass any fragment of SEQ ID NO:4 having at least 30 contiguous amino acids of SEQ ID NO:4 without regard as to any functional characteristic of the fragment. The specification further states on page 26, line 23 that the antigenic polypeptides identified from SEQ ID NO:4 are residues 62-101, 226-259 and 197-308. Claims 166-173 read on fragments of SEQ ID NO:4 which include fragments outside of the specific regions, such as fragments taken from residues 1-61 and residues 102-198. The specification fails to teach how to use said broadly claimed fragments of SEQ ID NO:4.

It is well known in the art that polypeptides are folded 3-dimensional structures, the function and stability of which are directly related to a specific conformation (Mathews and Van Holde, Biochemistry, 1996, pp. 165-171, cited in a previous Office action). In any given polypeptide, amino acids distant from one another in the primary sequence may be closely located in the folded, 3-dimensional structure (Mathews and Van Holde, Biochemistry, 1996, pp. 166, figure 6.1). The specific conformation of a polypeptide results from non-covalent interactions between amino acids, beyond what is dictated by the primary amino acid sequence. Fragments of SEQ ID NO:4 taken out of the context of the entirety of SEQ ID NO:4 can potentially have radically altered three dimensional structure relative to the corresponding three dimensional structure within the SEQ ID NO:4 environment (Matthews, B. "Genetic and Structural Analysis of the Protein Stability Problem", cited in a previous Office action). Thus, the consequences of the altered sequence environment cannot be predicted. Due to these reasons, one of skill in the art would be forced into undue experimentation in order to use the broadly claimed invention.

Further, it is recognized in the art (Burch WO 03/084467) that putative epitopes can be predicted using a computer to scan the sequence of a protein for amino acid sequences that contain a "motif" or a defined pattern of amino acid residues associated with a particular MHC allele, but that the vast majority of these predicted epitopes fail to be immunogenic (page 5, lines

18-21). Therefore, given the lack of teachings in the specification regarding how to use such a fragment of the claimed sequence which is not immunogenic, one of skill in the art would be subject to undue experimentation in order to use the broadly claimed fragments.

Applicant argues against the use of the publication of Burch (WO 03/084467) stating that it is not prior art. Applicants attention is drawn to Section 2124 of the M.P.E.P. wherein it is stated:

Exception to the Rule That the Critical Reference Date Must Precede the Filing Date
IN SOME CIRCUMSTANCES A FACTUAL REFERENCE NEED NOT ANTEDATE THE FILING DATE
In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. Some specific examples in which later publications showing factual evidence can be cited include situations where the facts shown in the reference are evidence "that, as of an application 's filing date, undue experimentation would have been required, In re Corneil, 347 F.2d 563, 568, 145 USPQ 702, 705 (CCPA 1965), or that a parameter absent from the claims was or was not critical, In re Rainer, 305 F.2d 505, 507 n.3, 134 USPQ 343, 345 n.3 (CCPA 1962), or that a statement in the specification was inaccurate, In re Marzocchi, 439 F.2d 220, 223 n.4, 169 USPQ 367, 370 n.4 (CCPA 1971), or that the invention was inoperative or lacked utility, In re Langer, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974), or that a claim was indefinite, In re Glass, 492 F.2d 1228,1232 n.6, 181 USPQ 31, 34 n.6 (CCPA 1974), or that characteristics of prior art products were known, In re Wilson, 311 F.2d 266, 135 USPQ 442 (CCPA 1962)." In re Koller, 613 F.2d 819, 823 n.5, 204 USPQ 702, 706 n.5 (CCPA 1980) (quoting In re Hogan, 559 F.2d 595, 605 n.17, 194 USPQ 527, 537 n.17 (CCPA 1977) (emphasis in original)).

Thus the MPEP supports the use of post-filing date references to support a rejection based on undue experimentation, which is the fact pattern in the instant rejection under 112, first paragraph regarding fragments of SEQ ID NO:4.

The rejection of claim 149 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 23 of U.S. Patent No. 6,027,916 is withdrawn due to a typographical error.

Claim 169 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 23 of U.S. Patent No. 6,027,916. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the '916 patent anticipates the instant claim 169.

All other rejections and objections as set forth or maintained in the previous Office action are withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen A. Canella whose telephone number is (571)272-0828. The examiner can normally be reached on 10-6:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571)272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Karen A. Canella, Ph.D.
02/18/2007